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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. 182 |
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| EXAMINER |
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| ART UNIT | PAPER NUMBER 4 |
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/543,782

Applicant(s)
ZUCKER-FRANKLIN AND PANCAKE

Examiner
CB Wilder

Group Art Unit
1655



☒ Responsive to communication(s) filed on Aug 8, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-10 is/are pending in the application.

Of the above, claim(s) 3-10 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 and 2 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 2, drawn to a method of screening to detect DNA, classified in class 435, subclass 6.
 - II. Claims 1 and 3, drawn to a method of screening to detect protein or antibody, classified in class 435, subclass 7.1.
 - III. Claim 4-10, drawn to method for screening pregnant women and nursing mother, classified in class 435, subclass .
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions I, II and III are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group I, II and III have different methods have different starting materials, different methodologies and different objectives. For example, the method of invention I is drawn to a screening method for detecting DNA related to a disease in an animal or human sample which would be expected to use, for example, polymerase chain amplification and/or Southern blotting techniques

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whereas the method of invention II is drawn to a screening method for detecting proteins and/or antibodies related to a disease in an animal or human sample which would be expected to use, for example, Western blotting and/or a heterogeneous or solid phase assay system, such as e.g., ELISA and invention III is drawn to a screening method exclusive to pregnant woman and nursing mothers to determine whether or not breast feeding should be discontinued. The searches for invention I, II and III are not coextensive because screening methods for detecting DNA and/or protein related to a disease are not usually combined art and are not limited to determining whether breast-feeding should be discontinued in pregnant women or nursing mothers. Therefore the different inventions are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention: DNA, protein and antibody.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

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including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Exr. finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Ms. Anne Kornbau on November 2, 2000 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 2 drawn to a method of screening to detect DNA and a species election drawn to DNA. Affirmation of this election must be made by applicant in replying to this Office action. Claim 3-10 are withdrawn from further consideration by the Exr., 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Priority

8. Applicant's claim for domestic priority under 35 U.S.C. 119(e) for provisional application 09/543,782, filed April 6, 1999 is acknowledged.

Abstract

9. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- (a) Claims 1 and 2 are incomplete because the claims lack essential elements and steps for detecting the presence of DNA in a sample, such as primers and probes for amplification and hybridization reactions as recited in the specification. Clarification is required.
- (b) Claims 1 and 2 lack proper antecedent basis for "when said test is positive" because a "positive" test is not defined in the claims.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Zucker-Franklin et al. (*Proc. Natl. Acad. sci. USA*, vol. 94 (12):6403-6407, June 1997). Regarding claims 1 and 2, Zucker-Franklin et al. teach a method of screening blood donors or potential blood donors for carriers of diseases or conditions related to HTLV-I and/or HTLV-II infection, comprising: subjecting each blood sample from the donors or potential donors to a test for the presence of DNA encoding the HTLV-I and/or HTLV-II Tax protein and determining that the donor is a carrier of a disease or condition related to HTLV-I and/or HTLV-II infection when said subjecting step is positive, without input from any other test results or screening test

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specifically provided to test for infection with either HTLV or HTLV-II (col. page 6404, columns 1, beginning at line 4 to col. 2 line 16, *see also page 6405, col. 1, lines 17-37*). Therefore the claimed invention of claims 1 and 2 is anticipated by the reference of Zucker-Franklin et al.

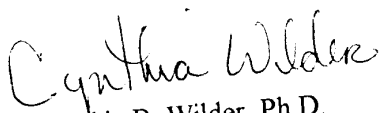
Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the Exr. should be directed to Exr. Cynthia Wilder whose telephone number is (703) 305-1680. The Exr. can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the Exr. by telephone are unsuccessful, the Exr.'s supervisor, W. Gary Jones, can be reached at (703) 308-1152. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed the Group's receptionist whose telephone number is (703) 308-0196.


Cynthia B. Wilder, Ph.D.

November 6, 2000

